

E-Filed 2/24/05

NOT FOR CITATION
IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

BIOGENEX LABORATORIES,

Plaintiff,

v.

VENTANA MEDICAL SYSTEMS, INC.,

Defendant.

Case Number C-03-3916-JF (PVT)

ORDER RE MOTIONS HEARD
SEPTEMBER 3, 2004

[Doc. Nos. 22, 23, 38, 44, 53]

Plaintiff BioGenex Laboratories, Inc. ("BioGenex") filed the complaint in this action on August 25, 2003, asserting ongoing infringement by Defendant Ventana Medical Systems, Inc. ("Ventana") of three BioGenex patents: U.S. Patent No. 6,451,551 ("the '551 patent"), U.S. Patent No. 5,578,452 ("the '452 patent") and U.S. Patent No. 5,244,787 ("the '787 patent"). Before the Court are five motions heard September 3, 2004: (1) Ventana's motion for summary judgment with respect to the '551 patent on the ground that BioGenex's preliminary infringement contentions filed March 15, 2004 do not assert infringement of the '551 patent; (2) BioGenex's motion to allow it to amend its preliminary infringement contentions to assert infringement of the '551 patent; (3) Ventana's motion for summary judgment of invalidity of the asserted claims of the '452 patent based upon publication more than one year before the asserted priority date; (4)

BioGenex's motion for leave to amend its preliminary infringement contentions to change the asserted priority date; and (5) BioGenex's motion for leave to file an amended complaint adding claims that Ventana is infringing a fourth patent, U. S. Patent No. 6,632,598 ("the '598 patent").

I. '551 PATENT

As its complaint reads presently, BioGenex alleges infringement of three patents: the '551 patent, the '452 patent and the '787 patent. This Court's Patent Local Rules require that, not later than ten days after the Initial Case Management Conference, a party claiming patent infringement must serve upon all parties a "Disclosure of Asserted Claims and Preliminary Infringement Contentions" (referred to herein as "preliminary infringement contentions"). Pat. L.R. 3-1. These preliminary infringement contentions must contain the following information: (a) each claim of each patent in suit that is allegedly infringed; (b) separately for each such claim, the products or instrumentalities that practice the claimed invention; (c) a chart identifying specifically where each element of each asserted claim is found within each accused product or instrumentality; (d) whether each element of each asserted claim is literally present in such product or instrumentality or present under the doctrine of equivalents; (e) for any patent that claims priority to an earlier application, the priority date to which each asserted claim allegedly is entitled; and (f) if a party claiming patent infringement wishes to assert that its own products or instrumentalities practice the claimed invention, the party must identify each such product or instrumentality.

BioGenex's preliminary infringement contentions originally were due on January 26, 2004. BioGenex subsequently received two extensions of time, and the preliminary infringement contentions ultimately were due on March 15, 2004. BioGenex served its preliminary infringement contentions on that date, asserting infringement of only the '452 patent and the '787 patent. With respect to the '551 patent, BioGenex did not assert infringement of any claims, identify any accused products, provide a patent infringement claim chart or do any of the other things required by Pat. L.R. 3-1. On April 27, 2004, Ventana filed a motion for summary judgment with respect to BioGenex's claims of infringement of the '551 patent, asserting that because BioGenex had failed to make any preliminary infringement contentions, it now is

1 precluded from asserting infringement.

2 On June 1, 2004, BioGenex served Ventana with late preliminary infringement
3 contentions with respect to the '551 patent and offered a proposed stipulation extending
4 Ventana's time to serve its Preliminary Invalidity Contentions with respect to all three patents in
5 suit. Ventana refused to accept BioGenex's late preliminary infringement contentions and
6 indicated its intention to proceed with its motion for summary judgment. On July 1, 2004,
7 BioGenex filed a motion for leave to amend its preliminary infringement contentions to add
8 disclosures and contentions regarding the '551 patent.

9 Pursuant to Pat. L.R. 3-7, a plaintiff may amend its preliminary infringement contentions
10 by order of the Court upon a showing of good cause. There is very little case law discussing
11 Rule 3-7 or the good cause requirement. The two published cases that do discuss the rule
12 emphasize that its purpose is to require parties to disclose their theories early in the litigation and
13 adhere to those theories once they have been disclosed. *Integrated Circuit Systems, Inc. v.*
14 *Realtek Semiconductor Co., Ltd.*, 308 F.Supp.2d 1106, 1107 (N.D. Cal. 2004); *LG Electronics,*
15 *Inc. v. Q-Lity Computer, Inc.*, 211 F.R.D. 360, 367 (N.D. Cal. 2002). This departure from
16 general policy favoring liberality of amendment in civil actions is designed to avoid the "shifting
17 sands" approach that sometimes was observed in patent litigation prior to adoption of the Patent
18 Local Rules. *Integrated Circuit Systems*, 308 F.Supp.2d at 1107; *LG Electronics*, 211 F.R.D. at
19 367.

20 While the Ninth Circuit has not offered any guidance as to what constitutes good cause to
21 amend preliminary infringement contentions under this Court's Patent Local Rules, it has
22 addressed the meaning of good cause in the context of a motion to amend a scheduling order. In
23 discussing Fed. R. Civ. P. 16(b), which requires good cause to modify a scheduling order in a
24 civil case, the Ninth Circuit has held that the focus must be on the diligence of the party seeking
25 amendment. *Johnson v. Mammoth Recreations, Inc.*, 975 F.2d 604, 609 (9th Cir. 1992).
26 "[C]arelessness is not compatible with a finding of diligence and offers no reason for a grant of
27 relief." *Id.* The existence or degree of prejudice to the opposing party may be considered;
28 however, the motion turns on the moving party's reasons for seeking modification. *Id.*

1 BioGenex explains its failure to provide timely preliminary infringement contentions by
2 stating that when such contentions were being prepared, “an issue arose” as to whether a
3 particular limitation found in claim 1 of the ‘551 patent was met by Ventana’s products. Rather
4 than provide preliminary infringement contentions in the face of its uncertainty, BioGenex
5 conducted further investigation. However, BioGenex did not seek an extension of time to file its
6 contentions but rather simply ignored the March 15, 2004 deadline. It took no action to inform
7 the Court or Ventana that investigations regarding the ‘551 patent were ongoing, even after
8 receiving Ventana’s motion for summary judgment in April 2004. BioGenex finally submitted
9 its preliminary infringement contentions to Ventana on June 1, 2004, without leave of court and
10 approximately two and one-half months after they were due. When Ventana attempted to
11 conduct discovery regarding BioGenex’s investigation regarding the ‘551 patent, in an effort to
12 determine whether BioGenex had been diligent in attempting to meet the March 15 deadline for
13 preliminary infringement contentions, BioGenex asserted privilege and refused to respond.

14 BioGenex asserts that it should be permitted to amend its preliminary infringement
15 contentions because Ventana would not be prejudiced by such amendment given the fact that no
16 claim construction hearing has been held. As discussed above, prejudice is a factor that may be
17 considered, but the focus of the Court’s inquiry must be on BioGenex’s own conduct. *Johnson*,
18 975 F.2d at 609. Moreover, Ventana would be prejudiced to the extent that BioGenex’s inaction
19 led Ventana to expend time and money in filing and pursuing the instant motion for summary
20 judgment. Ventana is poised to prevail on its motion absent intervention by the Court. The
21 Court nonetheless might be inclined to grant relief to BioGenex, perhaps conditioned upon
22 reimbursement of Ventana’s fees and expenses in connection with the instant motion for
23 summary judgment, had BioGenex made a reasonable showing of good cause. However, the
24 Court concludes on the record before it that BioGenex has not made such a showing.
25 Accordingly, the Court will grant Ventana’s motion for summary judgment of non-infringement
26 with respect to claims based upon the ‘551 patent and deny BioGenex’s motion for leave to
27 amend its preliminary infringement contentions.

II. '452 PATENT

On March 15, 2004, BioGenex timely served its preliminary infringement contentions with respect to the '452 patent, claiming infringement of claims 1, 2, 3 and 9 and expressly stating that for these claims "BioGenex does not claim priority beyond the application filing date of August 12, 1993."

On April 27, 2004, Ventana filed a motion for summary judgment of invalidity pursuant to 35 U.S.C. § 102(b), which provides that a patent claim is invalid if the subject matter of the claim was described in a printed publication more than one year before the priority date. Ventana asserts that the subject matter of the asserted claims was disclosed more than one year before the claimed priority date in an article entitled *A Technique for Retrieving Antigens in Formalin-fixed, Routinely Acid-decalcified, Celloidin-embedded Human Temporal Bone Sections for Immunohistochemistry*, authored by Shi, et al., and published in the June 1992 issue of *Journal of Histochemistry and Cytochemistry* ("Shi article"). The article was written by the inventors of the '452 patent and others, and appears to disclose each and every element of claims 1, 2, 3 and 9 of the '452 patent. Accordingly, the Shi article appears to invalidate those claims based upon the disclosed priority date of August 12, 1993.

On July 30, 2004, BioGenex filed a motion for leave to amend its preliminary infringement contentions to assert an earlier priority date of January 16, 1992 for claims 1, 2, 3 and 9. BioGenex also seeks to add infringement contentions with respect to claim 5 of the '452 patent, and to assert a January 16, 1992 priority date with respect to claim 5. The motion for leave to amend constitutes the entirety of BioGenex's opposition to Ventana's motion for summary judgment of invalidity. BioGenex does not dispute that the Shi article discloses each and every element of claims 1, 2, 3 and 9 of the '452 patent and renders those claims invalid based upon the disclosed priority date of August 12, 1993. However, BioGenex asserts that it is entitled to a priority date of January 16, 1992 because the '452 patent is a continuation-in-part of Application Serial Number 928,962 ("parent application"), filed August 12, 1992, which in turn is a continuation-in-part of Application Serial Number 821,931 ("grandparent application"), filed January 16, 1992. BioGenex also asserts that it omitted claim 5 from its preliminary

1 infringement contentions through inadvertence and that it should be permitted to amend its
2 preliminary infringement contentions to add contentions based upon claim 5.

3 As with the parties' motions with respect to the '551 patent, resolution of the motions
4 with respect to the '452 patent turns upon whether BioGenex has demonstrated good cause for
5 amendment pursuant to Pat. L.R. 3-7. If BioGenex is not granted leave to amend, Ventana will
6 prevail upon its motion for summary judgment of invalidity based upon the Shi article and the
7 disclosed priority date of August 12, 1993. If BioGenex is granted leave to amend, Ventana
8 cannot prevail upon its motion, because the Shi article was not published prior to the newly-
9 asserted priority date of January 16, 1992.

10 The Court concludes that BioGenex has not provided a satisfactory explanation as to why
11 it failed to disclose the earlier priority date or disclose claim 5 in its original preliminary
12 infringement contentions. According to BioGenex, it is clear as can be that the '452 patent is a
13 continuation-in-part of the parent application, which in turn is a continuation-in-part of the
14 grandparent application, and thus that BioGenex "is entitled to" the earlier priority date.
15 However, if the relationships between the patents indeed is so clear, it is entirely *unclear* why
16 BioGenex failed to claim the earlier priority date in its preliminary infringement contentions.
17 Ventana asserts that the relationships between the patents is not so clear and that BioGenex made
18 a strategic decision to claim the later priority date and thus avoid potentially thorny issues.
19 Ventana argues persuasively that it would be unfair and prejudicial to permit BioGenex to make
20 such a strategic decision, wait for Ventana to tip its hand as to its prior art investigation and
21 invalidity defenses, and then avoid an otherwise good motion for summary judgment by back-
22 dating the patent's priority date. With respect to its failure to include claim 5 originally,
23 BioGenex relies upon the declaration of Philipp Novales-Li to substantiate its claim of
24 inadvertence. However, when Ventana sought to take Dr. Novales-Li's deposition, BioGenex
25 asserted privilege.

26 BioGenex argues that Ventana would not be prejudiced if the proposed amendments were
27 permitted, because the case is not far advanced and no claim construction hearing has been held.
28 As discussed above, prejudice is a factor that may be considered, but the focus of the Court's

inquiry must be on BioGenex's own conduct. *Johnson*, 975 F.2d at 609. "[C]arelessness is not compatible with a finding of diligence and offers no reason for a grant of relief." *Id.* Based upon this record, it is impossible for the Court to conclude that BioGenex has acted diligently or demonstrated good cause for amendment. Moreover, Ventana would be prejudiced if the amendments were permitted. Ventana based its entire prior art inquiry and preliminary invalidity contentions, served June 3, 2004, upon the disclosed priority date of August 12, 1993. Ventana is in a position to obtain summary judgment with respect to the '452 patent based upon these efforts. Allowing BioGenex to amend its preliminary infringement contentions in order to negate Ventana's efforts, particularly in light of BioGenex's extremely weak showing with respect to good cause, would permit the very "shifting sands" approach that the Patent Local Rules were designed to avoid. Accordingly, the Court will grant Ventana's motion for summary judgment of invalidity with respect to the '452 patent *for purposes of this lawsuit only*, and will deny BioGenex's motion for leave to amend its preliminary infringement contentions.

III. '598 PATENT

BioGenex seeks leave to amend its complaint to add claims that Ventana is infringing the '598 patent, a fourth patent not asserted in the original complaint. The '598 patent was issued approximately six weeks after the instant lawsuit was filed. Ventana argues that BioGenex's delay of almost a year before seeking leave to amend is unexplained and prejudicial to Ventana, which has proceeded with the litigation on the three patents asserted. BioGenex argues that it acted reasonably in investigating potential claims under the '598 patent, that it sought amendment as soon as was practicable and that judicial economy favors litigation of the '598 patent along with the other three patents in suit.

Unlike BioGenex's motions for leave to amend its preliminary infringement contentions, which are governed by Pat. L.R. 3-7 and the relatively strict standards discussed above, BioGenex's motion for leave to amend its complaint is governed by the more liberal standard of Fed. R. Civ. P. 15(a), which provides that "leave shall be freely given when justice so requires." In deciding whether to grant leave to amend, the Court will consider several factors, including: (1) undue delay by the party seeking the amendment; (2) prejudice to the opposing party; (3) bad

1 faith; (4) futility of amendment; and (5) whether the party previously has amended its pleadings.
 2 *Bonin v. Calderon*, 59 F.3d 815, 845 (9th Cir. 1995).

3 It does appear that BioGenex delayed for a significant period of time before seeking leave
 4 to amend, and Ventana well may be prejudiced by such delay in that it has geared its defense of
 5 this action only to the three previously disclosed patents in suit. However, there is no evidence
 6 that BioGenex has acted in bad faith or that the proposed amendment would be futile. Nor has
 7 BioGenex previously sought to amend its complaint. Given the liberal standard of Rule 15(a),
 8 the Court would be inclined to permit the amendment if it were convinced that the '598 patent is
 9 sufficiently related to the remaining patent in suit, the '787 patent, that it would make sense to
 10 litigate the two patents in the same suit. However, BioGenex has not provided the Court with
 11 sufficient information to demonstrate that judicial economy warrants litigating the two patents in
 12 the same suit. Accordingly, the Court will deny BioGenex's motion for leave to amend its
 13 complaint. The Court expects that BioGenex simply will file a new lawsuit for infringement of
 14 the '598 patent. The Court's ruling is without prejudice to BioGenex filing a motion to relate or
 15 consolidate any such future action with the instant action. If BioGenex can demonstrate that the
 16 two actions in fact should be litigated together, the Court will permit such relation or
 17 consolidation.

18 IV. ORDER

- 19 (1) With respect to the '551 patent, Ventana's motion for summary judgment of non-
 20 infringement is GRANTED and BioGenex's motion for leave to amend its
 preliminary infringement contentions is DENIED;
- 21 (2) With respect to the '452 patent, Ventana's motion for summary judgment of
 22 invalidity is GRANTED for purposes of this lawsuit only and BioGenex's motion
 for leave to amend its preliminary infringement contentions is DENIED; and
- 23 (3) With respect to the '598 patent, BioGenex's motion for leave to amend its
 24 complaint is DENIED WITHOUT PREJUDICE to BioGenex filing a motion to
 relate or consolidate any future action with the instant action.

25 DATED: February 24, 2005

26 /s/ electronic signature authorized

27 JEREMY FOGEL
 28 United States District Judge

1 This Order was served on the following persons:

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